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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Igor Stagljär

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EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

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DELIVERY MODE

10/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,507	Applicant(s) STAGLJAR ET AL.	
	Examiner Michele K. Joike, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-76 is/are pending in the application.
- 4a) Of the above claim(s) 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-65, 68, 70-72, 75-76 is/are rejected.
- 7) ☒ Claim(s) 66, 67, 73 and 74 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/6/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed July 23, 2007.

Claims 48-76 are pending in the instant application. Claim 69 is withdrawn; claims 48-68 and 70-76 are examined. Any rejection of record in the previous Office Action, mailed January 22, 2007 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new rejection necessitated by amendment.

Claims 75 and 76 refer to the vector and the promoter from claim 48, however, there is more than one vector in the claim. It is unclear whether one or both vectors from claim 48 are being limited by a low expression promoter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-65 stand rejected under 35 U.S.C. 102(b) as being anticipated by Stagljär et al (PNAS 95: 5187-5192, 1998, specifically pp. 5187, 5191 and figure 2). This rejection is maintained for reasons of record in the previous office action mailed May 4, 2007. New claims 71 and 72 are added to the rejection as discussed below.

Response to Arguments Concerning Claim Rejections – 35 USC § 102(b)

Applicant's arguments filed July 23, 2007 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants claim bait and prey vectors that are maintained episomally. In contrast, Stagljär's bait vector is integrated into the yeast genome. Also, the new limitation of detecting the interaction between the first and second protein had been added as the last step of the method in claim 48, which Applicants argue will not occur if a strong promoter, such as ADH1, is used in a CEN/ARS vector.

These arguments are not found persuasive for the following reasons.

Stagljär teaches both bait vectors that are integrated, as well as maintained episomally (see p. 5190, second paragraph). Reporters are used to detect whether the

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interaction between the first and second proteins has occurred. (For example, see Figure 3.) Stagljär uses a variety of promoters; ADH1 is not mentioned as one of them.

New claims 71 and 72 are added to the rejection. Claims 48-65 stand rejected under 35 U.S.C. 102(b) as being anticipated by Stagljär et al (PNAS 95: 5187-5192, 1998, specifically p 5190 and Figure 3).

Applicants claim the bait vector being a low copy vector, wherein the vector is only present in 1-2 copies per cell.

Stagljär et al teach the CEN/ARS, which is a low copy vector present in only 1-2 copies per cell.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stagljär et al as applied to claims 48-65 and 71-72 above, and further in view of Ehrhard et al.

Applicants claim a method of identifying compounds for their ability to interfere with protein-protein interaction, using the kit. The compound is a pharmaceutical drug.

Stagljär et al teaches a split-ubiquitin system for detecting the interaction between two membrane bound proteins by introducing and coexpressing plasmids that encode the fusion proteins Ost-1-Nub or Nub-Alg5 with Wbp1-Cub-PLV into *S. cerevisiae* strain yeast cells carrying *lacZ* and *HIS3* reporter genes under the control of LexA-binding sites and testing cells for β -gal activity. The Ost1-Nub fusion protein consists of a portion of Ost1p ER membrane protein and the Nub module. The Nub-Alg5 fusion protein consists of the Alg5 ER membrane protein and the Nub module. The Wbp1-Cub-PLV protein consists of a portion of the Wbp1p ER transmembrane protein, the Cub module, and the PLV transcriptional activator (abstract, page 5187, right column, last paragraph to end of page 5189 and Figure 2). Thus, Stagljär et al teaches all the limitations of the recited claims. Stagljär et al teach all the features of claims 57-65 in combination, thereby anticipating the kit. They do not teach a method of identifying pharmaceutical drugs for their ability to interfere with protein-protein interaction.

Ehrhard et al (Nature Biotech. 18: 1075-1079, 2000, specifically pp. 1075 and 1078) teach a method of identifying compounds for their ability to interfere with protein-protein interaction. One of the proteins is a membrane-bound protein, and the other is soluble. Cells were plated and exposed to different amounts of synthetic α -factor to determine the effect on protein-protein interaction. Since the disclosure does not define pharmaceutical drug, synthetic α -factor is interpreted to be a pharmaceutical drug.

The ordinary skilled artisan, desiring to perform a method of identifying compounds for their ability to interfere with protein-protein interaction, would have been motivated to combine the teachings of Stagilar et al teaching a split-ubiquitin system for detecting the interaction between two membrane bound proteins, as described above, with the teachings of Ehrhard et al, teaching a method of identifying compounds for their ability to interfere with protein-protein interaction because the control of protein-protein interactions is a fundamental aspect of cell regulation. It would have been obvious to one of ordinary skill in the art to perform a method of identifying drugs for their ability to interfere with protein-protein interaction because Ehrhard et al teach this method could be used to identify new inhibitors that could lead to new drugs for the treatment of human disease. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

Claims 66, 67, 73 and 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.
Examiner
Art Unit 1636


DAVID GUZO
PRIMARY EXAMINER